

OTC Hand Sanitizer Recalls 21 October-2 December, 2020

FDA RECALLS CLASSIFIED FROM 21 OCTOBER THROUGH 2 DECEMBER, 2020*	
21 OCTOBER: DRUG-CLASS I	
<p>Smart Care HAND SANITIZER, Ethyl Alcohol 62%, packaged in 0.84 FL.OZ (25 mL), labeled as a) Paw Patrol (Item #: 92321-144, UPC 8 50016 92321 9, NDC 70108-042-01); b) JoJo Siwa Dreamer (Item #: 92320-144, UPC 8 50016 92320 2, NDC 70108-044-01); c) Hot Wheels (Item #: 92317-144, UPC 8 50016 92317 2, NDC 70108-045-01); d) Barbie (Item #: 92318-144, UPC 8 50016 92318 9, NDC 70108-046-01); e) Trolls (Item #: 92322-144, UPC 8 50016 92322 6, NDC 70108-047-01); and f) Minions (Item #: 92319-144, UPC 8 50016 92319 6, NDC 70108-043-01); Distributed by Ashtel Studios Inc., Ontario, CA 91761.</p>	
Code: All lots codes within expiry.	
Manufacturer:	ASHTEL STUDIOS, INC. Ontario, Canada
Recalled by:	Ashtel Studio by press release on 1 Oct., 2019; classified by FDA on 17 Nov.; voluntary recall ongoing.
Distribution:	Pouches of .84-Ounce.hand sanitizer were distributed to the following states: CA, IL, and Ontario, Canada; quantity N/A.
Reason:	Labeling: Not Elsewhere Classified. Container packaging is made, formed or filled to be misleading, resembling food and drink pouches
Recall numbers:	D-0098-2021
28 OCTOBER: DRUG-CLASS II	
<p>1) Panagel Hand Sanitizer, 70% Alcohol,16 Fl. Oz. (472 mL) bottle, Made in Guatemala, Distributed by Central Med Distribution, 6100 Hollywood Blvd, Hollywood FL 33024, NDC 78384-001-04, UPC 378384000016.</p>	
<p>2) Genesis Hand Sanitizer Gel, Topical Solution, Non Sterile Solution, 240 mL (8 FL OZ.) bottle, Manufactured by Genesis Partnership Company S.A., Guatemala, NDC 74484-002-02, UPC 7401037205773.</p>	
<p>3) Genesis Hand Sanitizer Gel, Topical Solution, Non Sterile Solution, 1 gallon (3785 mL) bottle, Manufactured by Genesis Partnership Company S.A., Guatemala, NDC 74484-002-04, UPC 7401037203427.</p>	
<p>4) Killz Germz Hand Sanitizer, Alcohol Gel, 450 mL (15 fl oz.) bottle, Manufactured by Genesis Partnership Company S.A., Guatemala, For: Killz Germz, LLC., 1912 R street NW, Washington DC, 20009, NDC 74625-003-04, UPC 7401037203250.</p>	
<p>5) Killz Germz Hand Sanitizer, Alcohol Gel, 1 Gallon (128 fl. oz.) bottle, Manufactured by Genesis Partnership Company S.A., Guatemala, For: Killz Germz, LLC., 1912 R street NW, Washington DC 20009, NDC 74625-003-05, UPC 7401037203427.</p>	
Code: 1) Lot #: 072120, Exp. 01/21/2022	
2) Lot #: 37009, Exp. 02/10/2021	

3) Lot #: 37009, Exp. 02/10/2021	
4) Lot #: 36748, 36818, 36697, Exp. 10/15/21 and 11/8/21	
5) Lot #: 36748, 36818, 36697, Exp. 10/15/21 and 11/8/21	
Manufacturer:	Genesis Partnership Company SA, Villa Nueva, Guatemala
Recalled by:	Genesis Partnership by letter on 11 Sept., 2020; classified by FDA on 19 Oct.; voluntary recall ongoing.
Distribution:	Nationwide in the US; 1) 33,480 bottles, 2) 15,000 bottles, 3) 5,040 bottles, 4) 5,320 bottles, 5) 8,600 bottles.
Reason:	1-3: CGMP Deviations: hand sanitizers were recalled because they were manufactured in the same facility as another hand sanitizer product with sub-potent ethanol levels. 4-5: Sub-Potent Drug; Killz GERMz was recalled due to sub-potent results. Testing revealed ethanol levels as low as 62% while labelled claim is 70%.
Recall numbers:	D-0037-2021 through D-0041-2021
25 NOVEMBER: DRUG-CLASS II	
<p>1) NuuxSan Instant ANTIBACTERIAL HAND SANITIZER, 70% Ethyl Alcohol (ethyl alcohol 70%), 8 fl oz. 237 mL bottle, Distributed by PCM North America LLC 9543 Bassonnet ST. STE 307, Houston, TX 77036, Made in Mexico, UPC 7 13620 00017 5</p> <p>2) Modesa INSTANT HAND SANITIZER with Moisturizers and Aloe Vera (ethyl alcohol 70% v/v) 8 fl oz (237 mL) bottle, Distributed by: Midwood brands, LLC 10611 Monroe RD. Mathews, NC 28105 Made in Mexico UPC 3 2251 38042 6</p> <p>3) Assured Instant Hand Sanitizer Aloe & Moisturizers (Ethyl Alcohol 70% v/v) 8 fl oz / 237 mL bottle, Distributed By: Greenbrier International, Inc. 500 Volvo Parkway, Chesapeake, VA 23320. Made in Mexico. UPC 639277928610</p> <p>4) Assured Instant Hand Sanitizer Vitamin E and Aloe (Ethyl Alcohol 70% v/v), 8 fl oz / 237 mL bottle, Distributed By: Greenbrier International, Inc. 500 Volvo Parkway, Chesapeake, VA 23320. Made in Mexico, UPC 639277928597</p> <p>5) NEXT ADVANCED ANTIBACTERIAL HAND SANITIZER (Ethyl Alcohol 70%), 8 FL OZ (236 ML) bottle, Made in Mexico, Distributed by: Genomma Lab USA Inc., Houston, TX 77027. UPC 6 50240 05357 3</p>	
Code: 1) all lots	
2) 1931104AL	
3) 1931102AL	
4) 1931101AL	
5) Lots ending in 1001,1002, 1003, 1004, 1005.	
Manufacturer:	Albek De Mexico S.A. De C.V., San Juan Del Rio, Mexico

Recalled by:	Albek De Mexico by press release on 30 July, 2020; classified by FDA on 17 Nov.;; voluntary recall ongoing.
Distribution:	US nationwide; 1) 1,441,548 bottles, 2) 2,760 bottles, 3) 27,000 bottles, 4) 19,992 bottles, 5) 4,598,788 bottles.
Reason:	CGMP Deviations: Next Advanced Antibacterial Hand Sanitizer was found to be below the label claim for ethanol content and contained methanol. Other products were recalled because they were manufactured in the same facility as the product found to contain methanol.
Recall numbers:	D-0078-2021 through D-0082-2021
2 DECEMBER: DRUG-CLASS II	
SYP Health Hand Sanitizer Alcohol Gel (ethyl alcohol) 70%, Net Wt. 16.91 FL OZ (500 mL) bottles, Biotecnologia, Educacion y Genetica, S.A. de C.V. Av. Quetra, UPC 9 780201 378624.	
Code: EXP MAY/2021.	
Manufacturer:	Biotecnologia, Educacion y Genetica, S.A., Mexico
Recalled by:	AA PRODUCTS INC., Laredo, TX, by letter on 24 Sept., 2020; classified by FDA on 23 Nov.;; voluntary recall ongoing.
Distribution:	Texas; 1,392 bottles.
Reason:	CGMP Deviations: product manufactured at the same facility that produced product that FDA sampled and found to be subpotent for ethanol and contained methanol.
Recall numbers:	D-0102-2021
<i>* No hand sanitizer recalls were included in the 4, 11 and 18 November updates to FDA's records.</i>	
<i>EDITORS' NOTE: Tabulation prepared from information provided by FDA. The agency has three classes of recalls. Class I - violative product poses reasonable probability of serious adverse health consequences or death; Class II - violative product may cause temporary or medically reversible adverse health consequences; probability of serious consequences remote; Class III - violative product not likely to cause adverse health consequences.</i>	